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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,881	12/09/2003	Carl D. Wahlstrand	1023-333US01	6687

28863 7590 12/11/2006

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EXAMINER	
REIDEL, JESSICA L	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,881	WAHLSTRAND ET AL.	
	Examiner	Art Unit	
	Jessica L. Reidel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *26 and 27* is/are withdrawn from consideration.

5)☒ Claim(s) *25* is/are allowed.

6)☒ Claim(s) *1-5,7-14 and 18-22* is/are rejected.

7)☒ Claim(s) *6,15-17 and 23* is/are objected to.

8)☒ Claim(s) *1-27* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/04, 06/05, 09/05, 02/01/06, 02/16/06, 02/16/06, 07/06, 10/06, 11/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, drawn to an implantable medical device, classified in class 607, subclass 36.

II. Claims 26-27, drawn to a method, classified in class 128, subclass 899.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. For example, the apparatus could be implanted into a patient by a physician/clinician and left alone such that the device is able to move with the relative motions of its implantation environment. Furthermore, the apparatus as claimed does not require manipulation of its configuration either before or after implantation.

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the Examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Jason Kelly on December 7, 2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-25. Affirmation of this election must be made by Applicant in replying to this Office action. Claims 26 and 27 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. Applicant should note that the large number of references in the attached information disclosure statement(s) (IDS) have been considered by the Examiner in the same manner as other documents in Office search files are considered by the Examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this Office Action.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4)(5) because reference character "443" has been used to designate both "an angle of interface" and an element of which the Examiner is unsure, for "443" is not mentioned in the description. The drawings are further objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include

the following reference sign(s) mentioned in the description: "310", "311", "312" and "442". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the Examiner, the Applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

8. The specification contains references to commonly owned patent applications without application numbers. The Examiner respectfully requests that this information be updated along with any other referenced applications without application numbers or referenced applications that have since issued.

9. The disclosure is objected to because of the following informalities: there appears to exists inadvertent typographical errors at pages 9 and 11. The Examiner suggests revising page 9, paragraph 36, line 5 to read "that permits the device 201". The Examiner also suggests revising page 11,paragraph 42, line 4 to read "implantable medical device 301". Appropriate correction is required.

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-3, 7, 8, 10 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Singer et al. (U.S. 5,638,832) (herein Singer). As to Claims 1-3 and 19-21, Singer discloses a subcutaneous implant, read as an implantable medical device 10 comprising a plurality of interconnected modules – control module 12 and display device 14, interconnected via electronic coupling 20 – each of the modules 12, 14 comprising a respective one of a plurality of housings (see Singer Abstract, Fig. 1, column 2, lines 38-50 and column 3, lines 2-3). Singer further discloses that the implantable medical device 10 may also comprise a biologically-inert substance, read as an overmold that at least partially encapsulates each of the housings and includes the electronic coupling, read as a motion reduction element 20. Specifically, Singer discloses that the modules 12 and 14 and the motion reduction element 20 may be located inside a biologically-inert capsule (see Singer column 2, lines 51-55). The Examiner takes the position that motion reduction element 20 "reduces intermodule motion" since the element 20 connects the modules together and does not allow them to move apart from one another (see Singer Figs. 1 and 3-4 column 1, lines 66-67, column 2, lines 1-2 and column 3, lines 9-16).

13. As to Claims 7, 8 and 10, Singer expressly discloses that the motion reduction element 20 comprises a wire-like element or a fiber. It is inherent that fiber optic links, such as those used by Singer comprise a fabric (see Singer column 3, lines 3-6).

14. Claims 1-3, 11, 13, 14 and 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Meltzer (U.S. 5,645,586). As to Claims 1-3 and 19-21, Meltzer discloses an implantable medical device 11 comprising a plurality of interconnected modules 23, 24 and 25, where each of the modules 23, 24 and 25 comprises a housing (i.e. titanium or stainless steel) (see Meltzer Fig. 1 and column 3, lines 5-54). Meltzer further discloses a hinge arrangement, read as a motion reduction element 40, located between two of the modules and coupled to at least one of the modules (see 41, 42 of Meltzer Fig. 4 and column 4, lines 35-44). The Examiner takes the position that motion reduction element 40 "reduces relative motion between at least two of the modules" since the element 40 connects the modules together and does not allow them to move apart from one another. Meltzer further discloses that the entire implantable medical device 11 may be coated with a biocompatible polymer, such as a silicone rubber, read as an overmold that at least partially encapsulates each of the housings (see Meltzer column 4, lines 44-48).

15. As to Claims 11, 13 and 14, Meltzer discloses that the motion reduction element 40 comprises a rod 34 and slot element and two ridged members (top and bottom of one housing segment for forming the slot) coupled to the rod 34 (see Meltzer Fig. 3, column 3, lines 65-67 and column 4, lines 1-35). The Examiner takes the position that the rod 34 and corresponding slot elements of the housings of the modules forms a geared hinge.

16. Claims 1-3, 7, 18-21 and 24 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Probst et al. (U.S. 7,103,415) (herein Probst). As to Claims 1-3, 7 and 19-21, Probst discloses an implantable medical device 10 comprising an electrochemical cell 12, read as a module and control circuitry 32, read as another module. Probst expressly discloses that the module 12 comprises a casing, read as a housing 14.

Although silent to module 32 comprising a specified "housing", it is inherent, or at least obvious to one having ordinary skill in the art, that module 32 also comprising a housing to protect whatever chips, resistors and other miscellaneous electrical components that exist within the module 32 and the Examiner makes reference to Probst Fig. 1. Probst discloses that the implantable medical device 10 further comprises a housing, read as an overmold 36 that at least partially encapsulates each of the modules 12 and 32. Probst specifies that modules 12, 32 are interconnected by lead 34. The Examiner takes the position that lead 34 is synonymous with Applicant's "motion reduction element to reduce relative motion between at least two of the modules" since lead 34 keeps the two modules 12 and 32 connected to each other and unable to move apart (see Probst Figs. 1-8, column 2, lines 20-67, columns 3-5 and column 6, lines 1-15).

17. As to Claims 18 and 24, Probst discloses that the device 10 may be a neurostimulator. (see Probst Figs. 1-8, column 1, lines 13-50, column 2, lines 20-67, columns 3-5 and column 6, lines 1-15).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Singer. Singer discloses the claimed invention as discussed above except that it is not specified that the motion reduction element 20 comprises a polymer. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the motion reduction element, comprising one or more wires, a fiber optic link or a direct plug-type connection as taught by Singer to comprise a polymer, since it was known in the art to enclose wires or similar type connections in a polymer insulation in an effort to prevent shorting of the electrical components.

21. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meltzer in view of Sanders (U.S. 5,554,194) (herein Sanders). Applicant differs from Meltzer in that the motion reduction element comprises a ball and socket element. The Examiner considers a ball and socket element for coupling two modules of an implantable medical device together and for allowing some degree of movement between the modules to be conventional and well known in the art with Sanders being but one example (see Snaders Abstract and columns 3-4).

Double Patenting

22. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection

is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

23. Claims 1-5, 18-22 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10-34, 36-45, 47-49, 51, 53-56 and 60-66 of copending Application No. 10/730,873 (Amended June 16, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the claims of Application No. 10/730,873 or an obvious variant thereof

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-5, 18-22 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-31 and 33-57 of copending Application No. 10/731,869 (Amended September 13, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the claims of Application No. 10/731,869 or an obvious variant thereof

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. Claims 1-5, 18-22 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-15 and 17-25 of copending Application No. 10/731,699 (Amended February 15, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are either a broadening of the scope of the claims of Application No. 10/731,699 or an obvious variant thereof

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

26. Claims 1-5, 18-22 and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638 (Amended November 16, 2005). Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are

either a broadening of the scope of the claims of Application No. 10/731,638 or an obvious variant thereof

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

27. Claim 25 is allowed.

28. Claims 6, 15-17 and 23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

Bardy et al. (U.S. 2002/0103510) teaches that it is known in the art of implantable medical devices to provide means for manipulating the device into a configuration.

Jarvik (U.S. 5,613,935) discloses a high reliability cardiac assist system, read as an implantable medical device comprising a plurality of interconnected modules.

Owens et al (US 4,972,846) discloses at least two modules comprising patch electrodes 10 and 11, each of the modules comprises a respective one of at least two housings, a coupling module comprising two lumens, lead wires 21 and 23, each of which comprises a co-axial lumen defined by structures 102 and 103 in Fig. 4, an overmold comprising silicone boot 18 that at least partially encapsulates each of the housing and the coupling module (see Fig. 1) where the

coupling module permits motion of the two modules along at least one axis of motion resulting from the motion of the heart.

30. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Jessica L. Reidel whose telephone number is (571) 272-2129. The Examiner can normally be reached on Mon-Thurs 8:00-5:30, every other Fri 8:00-4:30.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jessica L. Reidel 12/07/06
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